**EXPEDITED PROCEDURE-EXAMINING GROUP 3762**

**S/N 10/756,897** **PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant: James O. Gilkerson et al. | Examiner: Scott Getzow |
| Serial No.: 10/756,897 | Group Art Unit: 3762 |
| Filed: January 14, 2004 | Docket No.: 279.214US3 |
| Customer No.: 45458 | Confirmation No.: 3622 |

Title: IMPLANTABLE DEFIBRILLATORS WITH PROGRAMMABLE CROSS-CHAMBER BLANKING

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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
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Alexandria, VA 22313-1450

Appellant requests review of the final rejection of the above-identified application in the Final Office Action mailed July 26, 2010. No amendments are being filed with this request. A Notice of Appeal accompanies this request. Review is requested for the following reasons:

I. Claims 25-33 and 36 were rejected under 35 U.S.C. 102(b) over Levine et al. (U.S. Patent No. 5,776,167; hereinafter "Levine"). Appellant respectfully submits that the § 102(b) rejection was clearly erroneous and should be reversed.

Appellant respectfully submits that the Office Action fails to establish a *prima facie* showing of anticipation. Under MPEP § 2131, a claim is anticipated only if *each and every element* as set forth in the claim is found, and that such elements *must be arranged as required by the claim*, shown in *as complete detail as is contained in the claim*. Appellant also respectfully submits that the § 102(b) rejection is vague and fails to articulate where and how Levine discloses, teaches or even suggests each and every recitation of claims 25 and 37 and their respective dependent claims.

Claims 25 and 37 similarly recite the cross-chamber inhibiting, for a duration corresponding to an *adjustable blanking interval*, (1) sensing of an atrial electrical signal when received information indicative of a ventricular electrical signal includes a ventricular event; or (2) sensing of a ventricular electrical signal when received information indicative of an atrial signal includes an atrial event. Claims 25 and 37 also similarly recite that such an adjustable blanking period includes a preset refractory period and a noise window interval, the noise

window interval *derived from a difference between* the preset refractory period and the adjustable blanking interval.

The Office Action asserts that "as set forth in figure 5 of Levine, a blanking interval is activated to blank the ventricle when atrial signals are generated, followed by a relative blanking interval. The relative blanking interval can be considered the noise window of applicant's claims. The relative blanking interval can receive information indicative of a ventricular or atrial event, and ignore the information for the purpose of directing pacing therapy." The Office Action also asserts "Re the dependent claims, all of the claimed structure is considered encompassed by the device of Levine. For example, the blanking intervals can be programmed by a physician, see column 8:55+ which teaches that the blanking interval can be adjusted." (*See* Office Action at p. 2, § 1.)

Appellant cannot find in the cited portions of Levine any mention of cross-chamber blanking intervals that are *adjustable*, including both a *preset refractory period* portion and a *noise window* portion, with a total duration of the *adjustable* blanking interval and the *preset* portion used to determine the *noise window* portion. Instead, the cited portions of Levine (FIG. 5 and col. 8, ll. 55 *et seq.*) apparently only mention *disabling* a ventricular sense amplifier for an *absolute* blanking interval in response to application of an *atrial stimulation pulse*. There is no mention of inhibiting ventricular sensing more generally in response to an *atrial event* as recited in claims 25 and 37. For example, such an *atrial event* as presently recited could include either a pacing event *or an intrinsic sensed event*, unlike Levine. (See Levine at FIG. 5, as cited in the Office Action (mentioning applying atrial *stimulation* and *disabling* a ventricular sense amplifier during an *absolute blanking interval*).)

The cited portion of Levine mentions that a "maximum blanking interval" can be adjusted. (See Levine at col. 8, ll. 55 *et seq.* as cited by the Office Action). However, Levine's maximum blanking interval is not the same as the adjustable cross-chamber blanking interval of the present claims. The cited portion of Levine does not mention that its maximum blanking interval includes a *preset refractory period and a noise window interval,* with the noise window interval *determined by a difference between the preset refractory period and the adjustable blanking interval*, as recited or incorporated in the present claims. Instead, Levine's maximum blanking interval is merely an upper limit for Levine's "autoblanking" behavior. Levine

mentions that its "autoblanking" involves extending the blanking interval by "additional relative blanking intervals" until "(1) no signals are detected for an entire relative blanking interval" *or* "(2) the total duration of the blanking interval reaches a predetermined maximum blanking interval." (Levine at col. 8, ll. 52-57.) Thus, in the absence of signal detection during Levine's "relative blanking interval," the total duration of Levine's blanking interval never reaches the adjustable "maximum blanking interval." In either case, Levine's "maximum blanking interval" is apparently not used to determine (e.g., automatically calculate) a noise window interval, using a preset refractory period, as recited or incorporated in the present claims.

Accordingly, because the cited portions of Levine fail to teach or even suggest each and every element in claims 25 and 37, Appellant respectfully requests reversal of this clearly erroneous rejection.

II. Claims 37-45 were erroneously rejected under 35 U.S.C. 103(a) over Levine. Appellant respectfully submits that no *prima facie* case of obviousness has been shown, for reasons similar to those discussed above with respect to the erroneous § 102(b) rejection. Thus, Appellant respectfully requests reversal of the § 103(a) rejection.

Appellant also respectfully submits that the § 103(a) rejection over Levine is clearly erroneous and should be reversed because it appears to be conclusory and is almost entirely devoid of supporting factual assertions. (*See* M.P.E.P. § 2132, "II. The Basic Factual Inquiries of Graham v. John Deere Co.".) The Office Action asserts that "In addition to the comments made above, it is considered obvious to have a memory circuit that contains instructions for all of the steps outlined in claim 37." (Office Action at p. 2, § 2.) The Office Action also asserts that "such programming for a pacemaker is common in the art, since most IMDs are microprocessor based, and further no unexpected result would come from such circuit containing instructions as claimed." (*Id.*) Appellant respectfully submits that the Office Action has failed to articulate some rational underpinning supporting the § 103 rejection of claims 37-45, because the Office Action entirely omits any discussion of the majority of the recitations of claim 37, other than the memory circuit. Accordingly, Appellant respectfully requests reversal of this clearly erroneous rejection.

III. Claims 25-33 and 36-45 were erroneously rejected under 35 U.S.C. 103(a) over Lu (U.S. Patent No. 5,591,214) in view of Levine. Appellant respectfully submits that no *prima facie* case of obviousness has been shown, for reasons similar to those discussed above with respect to the erroneous § 102(b) rejection, and with respect to the § 103(a) rejection over Levine, because Lu and Levine fail to teach or even suggest the subject matter of claims 25, 37, or their respective dependent claims.

The Office Action first requests "[f]or a discussion of Lu, see previous office action. As mentioned above, Levine teaches the use of a noise window interval. To use such with the device of Lu would have been obvious in that such a combination would yield predictable results, and further the effects of crosstalk would be alleviated, as mentioned in the abstract of Levine." (Office Action at p. 3, § 3.) The previous Office Action, mailed January 15, 2010, asserts "Re claim 37, to use a memory with instructions is considered to be obvious and to have such explicitly done in Lu would not result in unpredictable operability. Re 34,35,46,47, to use a noise window is considered obvious . . . to prevent noise from being sensed as a legitimate signal, and the teaching of using a noise window in column 5 of Lu." (Office Action, mailed January 15, 2010, at pp. 2-3, § 2.)

Appellant respectfully submits that such assertions fail to provide a *prima facie* showing of obviousness, and amount to conclusory assertions almost entirely devoid of factual support. For example, such assertions fail to articulate an objective motivation for combining Lu with Levine, nor, even if somehow possible, how such a combination could be made. Moreover, the Office Action also fails to provide specific citations showing where each and every recitation of claims 25 and 37 are either disclosed, taught, or suggested. In the absence of such a disclosure, teaching, or suggestion, the Office Action fails to articulate any reason why claims 25, 37, or their respective dependent claims are nevertheless obvious over Lu in view of Levine. Accordingly, Appellant respectfully requests reversal of this clearly erroneous rejection.

In sum, Appellant respectfully requests reversal of the clearly erroneous rejections of claims 25, 37, and their respective dependent claims because Lu and Levine fail to disclose the subject matter of claims 25, 37, or their respective dependent claims. The Office Action fails to remedy such deficiencies with facts sufficient to fill the substantial gaps between Lu, Levine, and the subject matter of the present claims, and instead provides conclusory assertions of

obviousness. The Office Action also fails to articulate how Lu and Levine could somehow be combined, and fails to provide an objective motivation for such a combination, assuming that such a combination were even somehow possible.

## CONCLUSION

Appellant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone the undersigned at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date December 22, 2010

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